

Claims:

1. A stable oral composition comprising a therapeutically effective amount of desloratadine, a stabilizer selected from the group comprising an antioxidant, a pharmaceutically acceptable organic compound that provides an alkaline pH, an alkali metal salt, or mixtures thereof, and pharmaceutically acceptable excipients.
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2. A stable oral composition as claimed in claim 1, wherein said stabilizer is an antioxidant.
- 10 3. A stable oral composition as claimed in claim 2, wherein said antioxidant is used in an amount ranging from about 0.01% to about 5% by weight of the composition.
4. A stable oral composition as claimed in claim 1, wherein said stabilizer is a pharmaceutically acceptable organic compound that provides an alkaline pH.
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5. A stable oral composition as claimed in claim 4, wherein said pharmaceutically acceptable organic compound that provides an alkaline pH is used in an amount ranging from about 0.01% to about 5% by weight of the composition.
- 20 6. A stable oral composition as claimed in claim 1, wherein said stabilizer is an alkali metal salt.
7. A stable oral composition as claimed in claim 6, wherein said alkali metal salt is used in an amount ranging from about 0.01% to about 10% by weight of the composition.
- 25 8. A stable oral composition as claimed in claim 1, wherein the N-formyl impurity of desloratadine is less than 0.5%w/w, when stored at 40°C and 75% relative humidity over an extended period of time.
9. A stable oral composition as claimed in claim 1, wherein the composition does not undergo discoloration, when stored at 40°C and 75% relative humidity over an extended period of time.
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10. A stable oral composition as claimed in claim 2, wherein said antioxidant is selected from the group consisting of butylated hydroxytoluene, butylated hydroxyanisole, DL-alpha-tocopherol, propyl gallate, octyl gallate, ethylenediamine tetraacetate, ascorbyl palmitate, acetyl cysteine, ascorbic acid, sodium ascorbate, fumaric acid, lecithin and mixtures thereof.

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11. A stable oral composition as claimed in claim 10, wherein said antioxidant is butylated hydroxy toluene.

12. A stable oral composition as claimed in claim 4, wherein said pharmaceutically acceptable
10 organic compound that provides an alkaline pH is selected from the group consisting of primary, secondary and tertiary amines, cyclic amines, N,N'-dibenzylethylenediamine, diethanolamine, ethylenediamine, meglumine (N-methylglucamine), monosodium glutamate, polacrillin sodium, sodium alginate, and mixtures thereof.

15 13. A stable oral composition as claimed in claim 12, wherein said pharmaceutically acceptable
organic compound that provides an alkaline pH is meglumine.

14. A stable oral composition as claimed in claim 6, wherein said alkali metal salt is selected
from the group consisting of sodium and potassium salts of carbonates, phosphates, silicates,
20 sulfates, citrates and mixtures thereof.

15. A stable oral composition as claimed in claim 1, wherein said stabilizer is a mixture of
meglumine and butylated hydroxy toluene.

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